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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Customer Number: 41552
Atassi, M. Zouhair : Confirmation Number: 9880
Application No.: 10/821,669 / : Group Art Unit: 1653
Filed: April 09, 2004 : Examiner: Unassigned
For: BOTULINUM TOXIN A PEPTIDES AND METHODS OF PREDICTING AND
REDUCING IMMUNORESISTANCE TO BOTULINUM TOXIN THERAPY

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Jose R. Lopez, Jr.
Jose R. Lopez, Jr.

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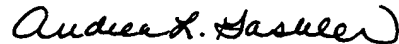
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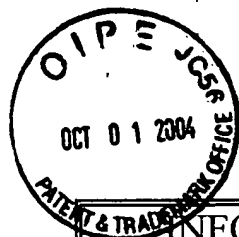
MCDERMOTT WILL & EMERY LLP



Andrea L. Gashler

Registration No. 41,029

4370 La Jolla Village Drive, Suite 700
San Diego, CA 92122
858.535.9001 ALG:JRL
Facsimile: 858.597.1585
Date: October 1, 2004
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U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	CITE NO.	Document Number Number-Kind Code ₂ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	1	US 4,551,435	11/05/1985	Liberti et al.	436/541		
	2	US 4,643,718	02/17/1987	Marten	604/28		
	3	US 6,676,622	01/13/2004	Strahilevitz	604/5.01		
	4	US 2004/0175385	09/09/2004	Marks et al.			
	5	US 2002/0155114	10/24/2002	Marks et al.			
FOREIGN PATENT DOCUMENTS							
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	6	Amersdorfer et al., "Genetic and immunological comparison of anti-botulinum type A antibodies from immune and non-immune human phage libraries," <u>Vaccine</u> 20:1640-1648 (2002).					
	7	Amersdorfer et al., "Molecular characterization of murine humoral immune response to botulinum neurotoxin type A binding domain as assessed by using phage antibody libraries," <u>Infect. Immun.</u> 65:3743-3752 (1997).					
	8	Aoki, "Pharmacology and immunology of botulinum toxin serotypes," <u>J. Neurol.</u> 248 Suppl. 1:3-10 (2001).					
	9	Atassi and Dolimbek, "Mapping of the antibody-binding regions on the HN-domain (residues 449-859) of botulinum neurotoxin A with antitoxin antibodies from four host species. Full profile of the continuous antigenic regions of the H-chain of botulinum neurotoxin A," <u>Protein J.</u> 23:39-52 (2004).					
	10	Atassi and Oshima, "Structure, activity, and immune (T and B cell) recognition of botulinum neurotoxins," <u>Crit. Revs. Immunol.</u> 19:219-260 (1999).					
	11	Atassi and Smith, "A proposal for the nomenclature of antigenic sites in peptides and proteins," <u>Immunochemistry</u> 15:609-610 (1978).					

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12	Atassi et al., "Cross-reaction of mouse antibodies against Tetanus neurotoxin with Botulinum neurotoxins A and B," <i>International Conference 2002, Basic and Therapeutic Aspects of Botulinum and Tetanus Toxins</i> , Hannover, Germany, June 8-12, Abstract R12 (2002).	
13	Atassi et al., "Localization and synthesis of the hormone-binding regions of the human thyrotropin receptor," <i>Proc. Natl. Acad. Sci. USA</i> 88:3613-3617 (1991).	
14	Atassi et al., "Mapping of the antibody-binding regions on botulinum neurotoxin H-chain domain 855-1296 with anti-toxin antibodies from three host species," <i>J. Prot. Chem.</i> 15:691-700 (1996).	
15	Atassi, "Immune recognition and cross-reactivity of botulinum neurotoxins," in <i>Scientific and Therapeutic Aspects of Botulinum Toxins</i> (edited by Brin et al.), pp. 385-408, Lippincott Williams and Wilkins, Philadelphia, PA (2002).	
16	Bavari et al., "Identifying the principal protective antigenic determinants of type A botulinum neurotoxin," <i>Vaccine</i> 16:1850-1856 (1998).	
17	Cenci Di Bello et al., "Antagonism of the intracellular action of botulinum neurotoxin type A with monoclonal antibodies that map to light-chain epitopes," <i>Eur. J. Biochem.</i> 219:161-169 (1994).	
18	Chen et al., "Antibody mapping to domains of botulinum neurotoxin serotype A in the complexed and uncomplexed forms," <i>Infect. Immun.</i> 65:1626-1630 (1997).	
19	Clayton and Middlebrook, "Vaccination of mice with DNA encoding a large fragment of botulinum neurotoxin serotype A," <i>Vaccine</i> 18:1855-1862 (2000)	
20	Clayton et al., "Protective vaccination with a recombinant fragment of <i>Clostridium botulinum</i> neurotoxin serotype A expressed from a synthetic gene in <i>Escherichia coli</i> ," <i>Infect. Immun.</i> 63:2738-2742 (1995).	
21	Dertzbaugh and West, "Mapping of protective and cross-reactive domains of the type A neurotoxin of <i>Clostridium botulinum</i> ," <i>Vaccine</i> 14:1538-1544 (1996).	
22	Dolimbek and Atassi, "Protection against alpha-bungarotoxin poisoning by immunization with synthetic toxin peptides," <i>Mol. Immunol.</i> 33:681-689 (1996).	
23	Dolimbek et al., "Cross reaction of tetanus and botulinum neurotoxins A and B and the boosting effect of botulinum neurotoxins A and B on a primary anti-tetanus antibody response," <i>Immunological Investigations</i> 31:247-262 (2002).	
24	Dressler et al., "Antibody-induced botulinum toxin therapy failure: Can it be overcome by increased botulinum toxin doses?" <i>Eur. Neurol.</i> 47:118-121 (2002).	
25	Goschel et al., "Botulinum A toxin therapy: Neutralizing and nonneutralizing antibodies—therapeutic consequences," <i>Exp. Neurol.</i> 147:96-102 (1997).	
26	Hambleton et al., "A possible common antigen on clostridial toxins detected by monoclonal anti-botulinum neurotoxin antibodies," 449-450 (1984).	
27	Jankovic, "Botulinum Toxin: Clinical Implication of Antigenicity and Immunoresistance," in Brin et al. eds., <i>Scientific and Therapeutic Aspects of Botulinum Toxin</i> , pp. 409-415, Lippincott Williams & Wilkins, Philadelphia, PA (2002).	
28	Klein, "Complications and adverse reactions with the use of botulinum toxin," <i>Dis. Mon.</i> 48:336-356 (2002).	

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29	Kozaki et al., "Development of antitoxin with each of two complementary fragments of <i>Clostridium botulinum</i> type B derivative toxin," <u>Infection and Immunity</u> 18:761-766 (1977).	
30	Kozaki et al., "Immunological characterization of Papain-induced fragments of <i>Clostridium botulinum</i> type A neurotoxin and interaction of the fragments with brain synaptosomes," <u>Infection and Immunity</u> 57:2634-2639 (1989).	
31	Kozaki et al., "The use of monoclonal antibodies to analyze the structure of <i>Clostridium botulinum</i> type E derivative toxin," <u>Infection and Immunity</u> 52:786-791 (1986).	
32	Kubota et al., "Epitope regions in the heavy chain of <i>Clostridium botulinum</i> type E neurotoxin recognized by monoclonal antibodies," <u>Applied & Environmental Microbiol.</u> 63:1214-1218 (1997).	
33	Lacy et al., "Crystal structure of botulinum neurotoxin type A and implications for toxicity," <u>Nat. Struct. Biol.</u> 5:898-902 (1998).	
34	LaPenotiere et al., "Expression of a large, nontoxic fragment of botulinum neurotoxin serotype A and its use as an immunogen," <u>Toxicon</u> 33:1383-1386 (1995).	
35	Middlebrook, "Protection strategies against botulinum toxin," in Atassi and Bixler (Eds.), <u>Immunology of Poreteins and Peptides VIII</u> p. 93-98 Plenum Press New York (1995)	
36	Mullaney et al., "Epitope mapping of neutralizing botulinum neurotoxin A antibodies by phage display," <u>Infect. Immun.</u> 69:6511-6514 (2001).	
37	Naumann et al., "Depletion of neutralizing antibodies resensitises a secondary non-responder to botulinum A neurotoxin," <u>J. Neurol. Neurosurg. Psychiatry</u> 65:924-927 (1998).	
38	Oshima et al., "Antibodies and T cells against synthetic peptides of the C-terminal domain (H _C) of botulinum neurotoxin type A and their cross-reaction with H _C ," <u>Immunol. Letters</u> 60:7-12 (1998).	
39	Oshima et al., "Immune recognition of botulinum neurotoxin type A: Regions recognized by T cells and antibodies against the protective H _C fragment (residues 855-1296) of the toxin," <u>Mol. Immunol.</u> 34:1031-1040 (1997).	
40	Pittman et al., "Antibody response to a delayed booster dose of anthrax vaccine and botulinum toxoid," <u>Vaccine</u> 20:2107-2115 (2002).	
41	Pless et al., "High-affinity, protective antibodies to the binding domain of botulinum neurotoxin type A," <u>Infect. Immun.</u> 69:570-574 (2001).	
42	Rosenberg et al., "Localization of the regions on the C-terminal domain of the heavy chain of botulinum A recognized by T lymphocytes and by antibodies after immunization of mice with pentavalent toxoid," <u>Immunol. Invest.</u> 26:491-504 (1997).	
43	Shyu et al., "DNA vaccination using the fragment C of botulinum neurotoxin type A provided protective immunity in mice," <u>J. Biomed. Sci.</u> 7:51-57 (2000).	
44	Simeckova-Rosenberg et al., "Protection of mice against lethal viral infection by synthetic peptides corresponding to B- and T-cell recognition sites of influenza A hemagglutinin," <u>Vaccine</u> 13:927-932 (1995).	
45	Simpson, "The study of clostridial and related toxins. The search for unique mechanisms and common denominators," <u>J. Physiol., Paris</u> 84:143-151 (1990).	
46	Spanoyannis et al., "Clostridium botulinum type B neurotoxin demonstrates cross-reactivity with antibodies from patients with cervical dystonia who no longer respond to type A neurotoxin treatment," <u>Developmental Medicine and Child Neurology</u> 40:33 Scientific poster SP:8 (1998).	

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	47	Tsuzuki et al., "Establishment of a monoclonal antibody recognizing an antigenic site common to <i>Clostridium botulinum</i> type B, C ₁ , D, and E toxins and tetanus toxin," <u>Infection and Immunity</u> 56:898-902 (1988).	
	48	Wu et al., "Characterization of neutralizing antibodies and identification of neutralizing epitope mimics on the <i>Clostridium botulinum</i> neurotoxin type A," <u>Appl. Environ. Microbiol.</u> 67:3201-3207 (2001).	
EXAMINER		DATE CONSIDERED	

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